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| TRANSMITTAL FORM (to be used for all correspondence after initial filing) | | Application Number | 10/650326 |
| | | Filing Date | August 28, 2003 |
| | | First Named Inventor | Keith A. Hruska |
| | | Art Unit | 1614 |
| | | Examiner Name | Not Yet Assigned |
| | | Attorney Docket Number | JJJ-P01-599 |
| Total Number of Pages in This Submission | 9 | | |

| ENCLOSURES (Check all that apply) | | |
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|--|--------------------------|----------|--------|
| Firm Name | ROPES & GRAY LLP | | |
| Signature | | | |
| Printed name | Ignacio Perez de la Cruz | | |
| Date | February 9, 2005 | Reg. No. | 55,535 |

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Dated: February 9, 2005 Signature: Linda Blake
(Linda Blake)

Docket No.: JJJ-P01-599
(PATENT)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of:
Hruska et al.

Application No.: 10/650326

Filed: August 28, 2003

For: CONJOINT ADMINISTRATION OF
MORPHOGENS AND ACE INHIBITORS IN
TREATMENT OF CHRONIC RENAL
FAILURE

Confirmation No.: 6882

Art Unit: 1614

Examiner: Not yet assigned

February 9, 2005

INFORMATION DISCLOSURE STATEMENT (IDS)

MS Amendment
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sir:

Pursuant to 37 CFR 1.56, 1.97 and 1.98, the attention of the Patent and Trademark Office is hereby directed to the references listed on the attached PTO/SB/08. It is respectfully requested that the information be expressly considered during the prosecution of this application, and that the references be made of record therein and appear among the "References Cited" on any patent to issue therefrom.

This Information Disclosure Statement is filed before the mailing date of a first Office Action on the merits as far as is known to the undersigned (37 CFR 1.97(b)(3)).

A copy of each reference on the PTO/SB/08 is attached, except the U.S. patents.

In accordance with 37 CFR 1.97(g), the filing of this Information Disclosure Statement shall not be construed to mean that a search has been made or that no other material information as defined in 37 CFR 1.56(a) exists. In accordance with 37 CFR 1.97(h), the filing of this Information Disclosure statement shall not be construed to be an admission that any patent,

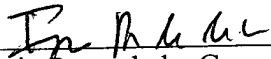
publication or other information referred to therein is "prior art" for this invention unless specifically designated as such.

It is submitted that the Information Disclosure Statement is in compliance with 37 CFR 1.98 and the Examiner is respectfully requested to consider the listed references.

The Director is hereby authorized to charge any deficiency in the fees filed, asserted to be filed or which should have been filed herewith (or with any paper hereafter filed in this application by this firm) to our Deposit Account No. 18-1945, under Order No. JJJ-P01-599. A duplicate copy of this paper is enclosed.

Dated: February 9, 2005

Respectfully submitted,

By 
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Substitute for form 1449A/B/PTO

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

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| Application Number | 10/650326 |
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| First Named Inventor | Keith A. Hruska |
| Art Unit | 1614 |
| Examiner Name | Not Yet Assigned |
| Attorney Docket Number | JJJ-P01-599 |

Sheet 1 of 3

U.S. PATENT DOCUMENTS

| Examiner Initials* | Cite No. ¹ | Document Number | Publication Date MM-DD-YYYY | Name of Patentee or Applicant of Cited Document | Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear |
|-----------------------|--------------------------|--|--------------------------------|--|---|
| | | Number-Kind Code ² (if known) | | | |
| | AA | US-5,011,691 | 04-30-1992 | Oppermann et al. | |
| | AB | US-5,266,683 | 11-30-1993 | Oppermann et al. | |
| | AC | US-4,968,590 | 11-06-1990 | Kuberasampath et al. | |
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| | AG | US-5,733,441 | 03-03-1998 | Higley et al. | |
| | AH | US-6,120,760 | 09-19-2000 | Hotten et al. | |
| | AI | US-6,498,142 | 12-24-2002 | Sampath et al. | |

FOREIGN PATENT DOCUMENTS

| Examiner Initials* | Cite No. ¹ | Foreign Patent Document | Publication Date MM-DD-YYYY | Name of Patentee or Applicant of Cited Document | Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear | T ⁶ |
|-----------------------|--------------------------|---|-----------------------------------|--|---|----------------|
| | | Country Code ³ -Number ⁴ -Kind Code ⁵ (if known) | | | | |
| | BA | WO 92/15223 | 10-17-1991 | Amgen Inc. | | |
| | BB | WO 93/04692 | 03-18-1993 | Creative Biomolecules, Inc. | | |
| | BC | WO 94/03200 | 02-17-1994 | Creative Biomolecules, Inc. | | |
| | BD | WO 98/50060 | 11-12-1998 | Creative Biomolecules, Inc. | | |
| | BE | WO 97/41880 | 11-13-1997 | Creative Biomolecules, Inc. | | |

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NON PATENT LITERATURE DOCUMENTS

| Examiner Initials* | Cite No. ¹ | Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published. | T ² |
|-----------------------|--------------------------|---|----------------|
| | CA | VUKICEVIC et al., "Developing Human Lung and Kidney are Major Sites for Synthesis of Bone Morphogenetic Protein-3 (Osteogenin)", (1994), J. Histochem. Cytochem. 42:869-875 | |
| | CB | JONES, et al., "Involvement of Bone Morphogenetic Protein-4 (BMP-4) and Vgr-1 in morphogenesis and neurogenesis in the mouse", (1991) Development 111: 531-542 | |
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| | CD | OZKAYNAK, et al. (1992) "Osteogenic Protein-2 A New Member of the Transforming Growth Factor- β Superfamily Expressed Early in Embryogenesis", J. Biol. Chem. 267: 25220-25227) | |
| | CE | OZKAYNAK, et al., "Murine Osteogenic Protein (OP-1): High Levels of mRNA in Kidney", (1991) Biochem. Biophys. Res. Commun. 179: 116-123. | |
| Examiner Signature | | Date Considered | |

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| Substitute for form 1449A/B/PTO INFORMATION DISCLOSURE STATEMENT BY APPLICANT <i>(Use as many sheets as necessary)</i> | | | | Complete if Known | |
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| | | | | Art Unit | 1614 |
| | | | | Examiner Name | Not Yet Assigned |
| Sheet | 2 | of | 3 | Attorney Docket Number | JJJ-P01-599 |

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| CF | HRUSKA, K.A., et al., 2000. "Osteogenic protein-1 (OP-1) prevents renal fibrogenesis associated with ureteral obstruction", Am J Phys (Renal) 279:F130-F143 |
| CG | LUO, G., et al., 1995. "BMP-7 is an inducer of nephrogenesis, and is also required for eye development and skeletal patterning" Genes Dev. 9:2808-2820. |
| CH | DUDLEY, A.T., et al., 1995. "A requirement for bone morphogenetic protein-7 during development of the mammalian kidney and eye". Genes Dev 9:2795-2807 |
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| CU | BRENNER et al. 1994 "Chronic Renal Failure" In Harrison's Principles of Internal Medicine, 13 th Edition, Isselbacher et al. (eds.), McGraw-Hill, Inc. New York pp. 1274-1281 |
| CV | GLASSOCK et al 1994 "Immunopathogenic Mechanisms of Renal Injury". In Harrison's Principles of Internal Medicine, 13 th Edition, Isselbacher et al. (eds.) McGraw-Hill, Inc. New York pp. 1292-1295 |
| CW | BOWIE et al. Deciphering the message in protein sequences: tolerance to amino acid substitutions. Science, (1990 March) 247(4948) 1306-10. |
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| CY | COE et al. "Approach to the patient with diseases of the kidney and urinary tract", Chapter 237, Harrison's Principles of Internal Medicine, 13 th ed. Isselbacher et al (eds). New York, McGraw-Hill, p 1252, 1994 |
| CZ | GLASSOCK, R.J. "Immunosuppressive treatment in the prevention of renal failure in primary glomerular diseases", Clinical and Experimental Dialysis and Apheresis, (1981) 5 (1-2) 21-46 |

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| | | | Examiner Name | Not Yet Assigned | |
| Sheet | 3 | of | 3 | Attorney Docket Number | JJJ-P01-599 |

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| CA1 | CARPENTER et al., "Dialysis and transplantation in the treatment of renal failure", Chapter 238, Harrison's Principles of Internal Medicine, 13 th ed. Isselbacher et al. (eds). New York, McGraw-Hill, page 1281, 1994 | |
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| CE1 | WATANABE et al, "Production of hydrogen peroxide by neutrophilic polymorphonuclear leukocytes in patients with diabetic nephropathy", Journal of Clinical Laboratory Analysis", (1993) 7 (4) 209-13 | |
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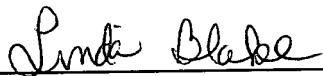
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